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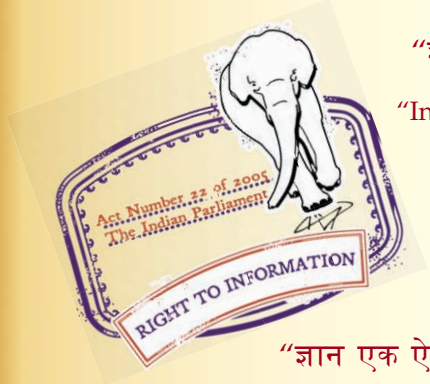
IS 6466 (1989): Thoracic and Cardiovascular Surgery Instruments - Needle Holders [MHD 6: Thoracic and Cardiovascular Surgery Instruments]



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"Knowledge is such a treasure which cannot be stolen"

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IS 6466 : 1989
(Reaffirmed 2005)

Indian Standard

THORACIC AND CARDIOVASCULAR SURGERY INSTRUMENTS — NEEDLE HOLDERS — SPECIFICATION

(First Revision)

भारतीय मानक

वक्ष एवं हृदय वाहिका शल्य चिकित्सा यंत्र – सूई-धारक – विशिष्टि

(पहला पुनरीक्षण)

UDC 615·472·2 : 617·54

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

May 1990

Price Group 2

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on 19 May 1989 after the draft finalized by the Thoracic and Cardiovascular Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first issued in 1972. In this revision, tolerances on various dimensions have been specified, requirements of the performance test have been altered, load closure test and an additional test for flexibility have been incorporated and the clauses on surface condition, marking and packing have been modified. Besides, a recommended sampling plan has been added.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

THORACIC AND CARDIOVASCULAR SURGERY INSTRUMENTS — NEEDLE HOLDERS — SPECIFICATION

(First Revision)

1 SCOPE

1.1 This standard prescribes requirements and tests for Gerbode's pattern and De Backey's pattern (3 mm jaw) needle holders used in thoracic surgery.

2 REFERENCES

2.1 The following Indian Standards are necessary adjuncts to this standard:

IS No.	*Title*
IS 1501 (Part 1) : 1984	Method for Vickers hardness test for metallic materials: Part 1 HV 5 to HV 100 (*second revision*)
IS 3642 : 1978	General requirements for surgical instruments (*first revision*)
IS 4905 : 1968	Methods for random sampling
IS 6528 : 1972	Specification for stainless steel wire
IS 6603 : 1972	Specification for stainless steel bars and flats
IS 7531 : 1975	Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments

3 MATERIAL

3.1 The instrument shall be made of stainless steel conforming to Designation 30Cr13 of IS 6603 : 1972.

3.2 Pin

The pin in the instrument shall be made of stainless steel conforming to Designation 20Cr13 or 30Cr13 of IS 6603 : 1972.

4 SHAPE AND DIMENSIONS

4.1 The shape and dimensions of the instrument shall be as shown in Fig. 1 and 2.

4.2 Tolerances

Tolerances on various dimensions shall be as given below:

±0·5 mm on dimensions up to 2·0 mm;

±0·1 mm on dimensions above 2·0 mm and up to 5·0 mm;

±0·2 mm on dimensions above 5·0 mm and up to 20·0 mm;

±0·5 mm on dimensions above 20·0 mm and up to 50·0 mm;

±1·0 mm on dimensions above 50·0 mm and up to 100·0 mm;

±2·0 mm on dimensions above 100·0 mm.

4.2.1 The two halves of the instruments shall, however, not differ at any dimension and shall match with each other perfectly.

5 MASS

5.1 The mass of the instrument of Gerbode's pattern shall be 35 to 45 g and that of the De Backey's pattern (3 mm Jaw) shall be 45 to 55 g.

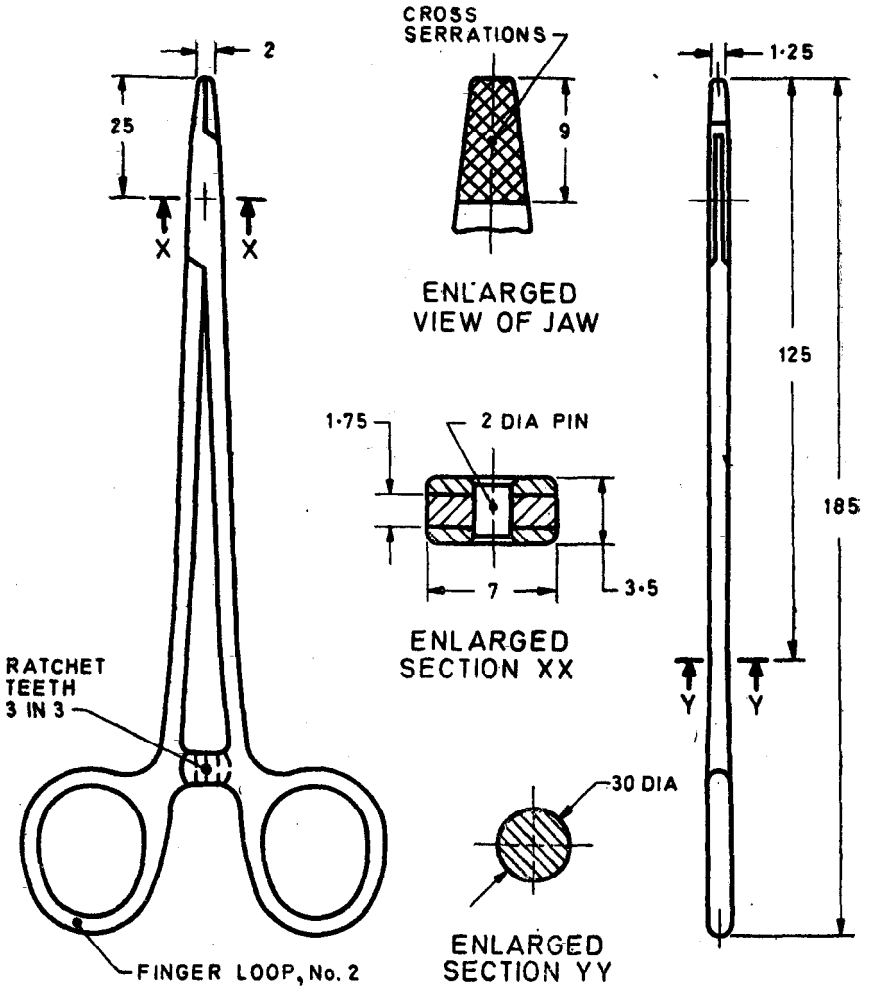
6 HEAT TREATMENT

6.1 The instruments shall be uniformly hardened and tempered to a hardness of 400 to 460 HV, when tested in accordance with IS 1501 (Part 1) : 1984.

6.2 Mating surfaces on the same instrument, such as opposite jaws and shanks shall not vary in hardness by more than 40 HV.

7 WORKMANSHIP

7.1 The needle holder shall be symmetrical and balanced. The opening and closing movement shall be smooth and jerk free.



All dimensions in millimetres.

FIG. 1 NEEDLE HOLDER, GERBODE'S PATTERN

7.2 The joint shall conform to the relevant requirements of **6** of IS 3642 : 1978.

7.3 The serrations on the jaws shall conform to the relevant requirements of Section 1 of IS 3642 : 1978.

7.4 The ratchet teeth shall conform to Section 3 of IS 3642 : 1978. The arms shall be symmetrical about the axis at every ratchet engagement.

7.5 The finger loops shall be in accordance with the relevant requirements of Section 5 of IS 3642 : 1978.

7.6 All edges shall be smooth and even.

8 SURFACE CONDITION

8.1 General

All surfaces shall be free from pores, crevices and grinding marks. The instrument shall be applied free from residual scale, acid, grease, grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

8.2 Surface Finish

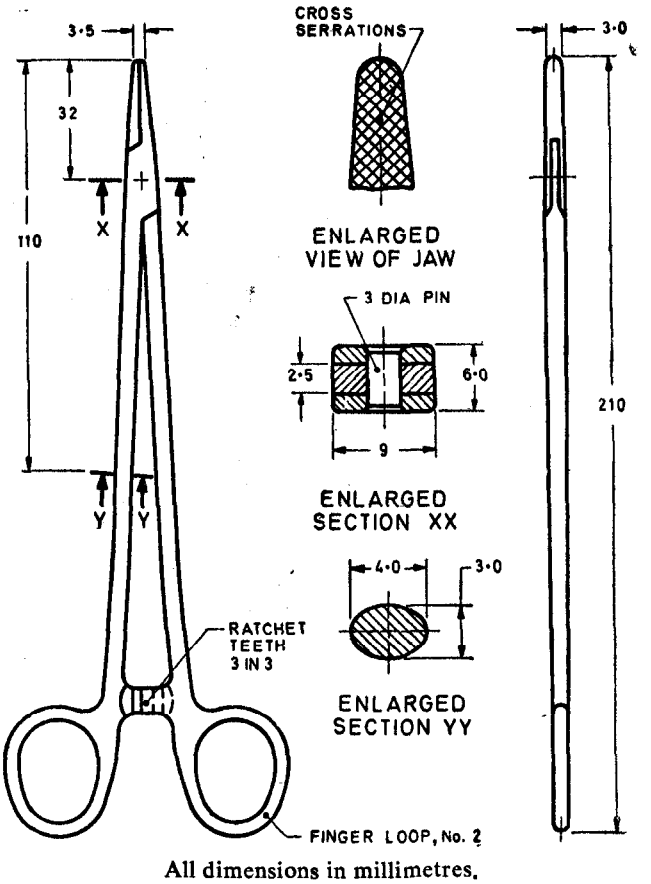
The surface finish of the instrument shall be reflection-reducing, for example satin finish, matt black finish.

NOTE — The satin finish should be effected by an appropriate procedure, such as grinding brushing, electropolishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and it should reduce glare.

8.3 Passivation and Final Treatment

The instruments shall be treated by a suitable passivation process, for example by electropolishing or by treatment with 10 percent (*v*/*v*) nitric acid solution for not less than 30 minutes at a temperature not less than 10°C and not exceeding 60°C. The instruments shall then be rinsed in water and dried in hot air.

NOTE — If the joint is lubricated, the lubricant should be non-corrosive and suitable for medical application according to the Indian Pharmacopoeia.



All dimensions in millimetres.

FIG. 2 NEEDLE HOLDER, DE BACKEY'S PATTERN (3 mm JAW)

9 TESTS

9.1 Performance Test

A plastics fibre (for example a suture filament) of maximum diameter 0·2 mm shall be placed between the jaws of the instrument at a point within one third of the length nearer to the tip. The instrument shall be fully closed and a tensile force of 20 N applied to the fibre. The fibre shall not slip out, irrespective of whether the direction of the load is longitudinal or transverse.

9.2 Load Closure Test

By fixing one finger loop of the needle holder in a vice, load shall be applied at the other finger loop by means of a pan or spring balance. The load at which the first ratchet just engages shall be noted. The load required to close the needle holder at the first step of the ratchet shall be 7 to 12 N (0·7 to 1·2 kgf approximately).

9.3 Flexibility Test

9.3.1 One arm of the needle holder shall be fixed in a vice at a point under the joint so that the arm protrudes from the upper surface of the vice jaws by an amount as follows:

Type of Needle Holder	*Distance of Pole of Finger Loop Point of Application of Load from Vice Jaws*	*Deflection*
	(mm)	(mm)
(1)	(2)	(3)
Gerbode's pattern	100	12
De Backey's pattern	125	15

By the application of gradual force at the upper pole of the finger loop, the shank of the needle holder shall be deflected in a plane at right angle to that of the finger loop by the amount shown in col 3 above as measured at the upper extremity of the clamped arm (that is, at the upper pole of the finger loop). On release of the force, no permanent set shall be observed. The test shall be repeated on the same arm with the finger loop fixed at its equator in the vice and the shank projecting above the vice. The deflecting force shall be applied to the shank at the point

mentioned above and shall act in a plane at right angles to that of the finger loop. The shank shall be deflected by the amount shown above as measured at the level of the point where the force is applied. On release of the force, the forceps shall not take a permanent set. The complete test shall be repeated on the opposite arm.

9.3.2 A stainless steel wire of 1 mm dia, conforming to Designation 04Cr18Ni10 of IS 6528 : 1972 shall be placed between the tips of the instrument jaws. The instrument shall be fully closed to the last ratchet position and left in this position for 3 hours at room temperature. After the test, no distortion, cracks or any other permanent modification in the instrument shall be visible.

9.4 Corrosion Resistance Test

The instruments shall be tested in accordance with IS 7531 : 1975. They shall show no sign of corrosion after the test.

10 MARKING AND PACKING

10.1 The instruments shall be legibly and indelibly marked with the manufacturer's name, initials or recognized trade-mark; the words 'stainless steel' or letters 'ss'; and the country of manufacture.

10.2 Each instrument shall be wrapped in a suitable cushioning materials like folded tissue paper. It shall then be put in a polyethylene bag or wrapped in wax paper. The instruments shall thereafter be packed in cartons in accordance with the current trade practice.

10.2.1 Alternatively, the instruments may be packed as agreed to between the purchaser and the supplier.

10.3 The packages shall be marked with the name and pattern of the instrument; the manufacturer's name, initials or recognized trade-mark; the words 'stainless steel', and the country of manufacture.

11 SAMPLING

11.1 The scale of sampling and criteria for conformity of the instruments to the requirements of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

ANNEX A

(*Clause* 11.1)

SAMPLING OF NEEDLE HOLDERS FOR THORACIC SURGERY

A-1 LOT

A-1.1 In any consignment, all the instruments of the same pattern, produced from the identical material under similar conditions and having the same surface finish shall constitute a lot.

A-2 SAMPLING

A-2.1 The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

Table 1 Scale of Sampling

(*Clauses* A-2.1, A-3.1 *and* A-3.2)

Lot Size	Sample Size	Sub-Sample Size
(1)	(2)	(3)
Up to 15	2	1
16 to 50	3	1
51 to 150	5	2
151 and above	8	3

A-2.2 These instruments shall be selected from the lot at random and in order to ensure randomness of selection, procedures given in IS 4905 : 1968 may be followed.

A-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 All the instruments selected according to col 1 and 2 of Table 1 shall be examined for shape and dimensions, workmanship, surface condition (visual) and tested for mass. An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as conforming to these requirements if no defective is found in the sample.

A-3.2 The lot having been found satisfactory according to **A-3.1** shall be further tested for other requirements. For this purpose a sub-sample of size given in col 3 of Table 1 shall be taken. These instruments in the sub-sample may be selected from those already examined according to **A-3.1.** Each instrument in the sub-sample shall be subjected to hardness, performance, load closure, flexibility and corrosion resistance tests. The lot shall be declared as conforming to the requirements of the specification if none of the instruments in the sub-sample fails in any of these tests.

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